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Original Research Article

Routine episiotomy versus selective episiotomy in nulliparous women at term-randomized comparative trial

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ABSTRACT

Background: Practice of routine episiotomy is debatable. The study aims to compare maternal and fetal outcome in routine episiotomy versus selective episiotomy in nulliparous women delivering at term.

Methods: Two hundred nulliparous women at term were assigned randomly to receive routine or selective episiotomy during delivery. The primary outcome measures were anterior vaginal trauma, 1st degree perineal tear, 2nd degree perineal tear, 3rd degree perineal tear, 4th degree perineal tear and Apgar score at 1 and 5 minutes. Secondary measures of outcome included consumption of analgesics, anal incontinence, urinary incontinence and dyspareunia.

Results: The episiotomy rate was 90% in routine episiotomy group and 42% in selective episiotomy group. Occurrence of second-degree perineal injury was more common in routine episiotomy group (90% versus 64%; $p < 0.0001$). However, there was no difference in occurrence of 3rd degree perineal tear among the groups. More women in selective episiotomy group suffered from anterior vaginal wall tear (22% versus 54% $p < 0.0001$). There was no difference among the groups in Apgar score, severity of perineal pain, analgesic use on day 2 of delivery, anal incontinence, urinary incontinence, dyspareunia and NICU admission of the neonate.

Conclusions: Routine episiotomy is associated with a higher incidence of perineal injuries without any added benefit for the mother and the baby.

Keywords: Episiotomy, Perineal tear, Routine episiotomy, Selective episiotomy

INTRODUCTION

Throughout the world the rates of episiotomy increased substantially during early 20th century. It was thought that episiotomy had several maternal and neonatal benefits such as reduced risk of perineal trauma, better wound healing, reduced risk of subsequent pelvic floor dysfunction, prolapse, urinary incontinence, fecal incontinence, sexual dysfunction and decreased chance of fetal asphyxia, cranial trauma, cerebral haemorrhage and mental retardation.

However the practice of routine episiotomy was introduced without strong scientific evidence of its effectiveness and its efficacy was questioned in 1980.¹ With the publication of several descriptive and analytical

papers assessing the effectiveness of episiotomy in preventing deep perineal lacerations (third and fourth degree), it was determined that, paradoxically, instead of playing a protective role for those events, episiotomy actually favored their occurrence.² So the policy of 'selective' use of episiotomy was introduced where the use of episiotomy is restricted rather than universally performed. In this policy clinicians use their clinical judgement to determine the need for episiotomy in conditions such as impending severe perineal tear, prolonged second stage of labour, shoulder dystocia, instrumental delivery, and non-reassuring fetal heart rate. Current evidence suggests that in women where no instrumental delivery is intended, selective episiotomy policies result in fewer women with severe perineal/vaginal trauma.³

However, the prevailing practice in our institute was routine episiotomy for delivering baby in nulliparous women. So, we felt a need to compare routine episiotomy with selective episiotomy in our set up in nulliparous women delivering at term.

METHODS

This randomized comparative trial was conducted from April 2014 to March 2015 at the Department of Gynecology and Obstetrics of Nil Ratan Sircar Medical College, Kolkata. All participants provided written informed consent before enrollment. Institutional Ethics Committee approved the protocol.

Inclusion criteria

Women were eligible for entry into the trial if they were nulliparous with a singleton pregnancy with vertex presentation at term (>37 weeks) and were allowed for vaginal delivery.

Exclusion criteria

Women were excluded from the trial if they had any such conditions like multiparity, multiple pregnancy, assisted breech delivery, non-vertex presentations including malposition, associated systemic diseases, BMI>30, maternal exhaustion, preterm deliveries, foetal macrosomia, premature rupture of membranes, vaginal delivery after caesarean (VBAC).

Randomization schedule

Randomization was done by simple randomization method using a table of random numbers (Fisher RA and Yates F). The schedule was constructed so that the number in each group would be balanced for every 10 women recruited. The group assignments were put into sealed envelopes. The envelopes were opened during the second stage of labour, and patients were assigned either to routine episiotomy or the selective episiotomy group, depending on the basis of the randomization sequence.

Treatment schedule

Under the policy of routine use of episiotomy, all nulliparous women were given an episiotomy. Under the policy of selective use of episiotomy, great restraint was observed in giving an episiotomy, for nullipara. In the group of selective episiotomies, the assistant doctors opted for an episiotomy if the woman had instrumental delivery, shoulder dystocia, and non-reassuring fetal heart rate. When indicated, only a mediolateral episiotomy was given in our hospital. In routine episiotomy group, after preparing patients by standard method, right mediolateral episiotomy was given after infiltrating the perineum with local anaesthesia (2% xylocaine). After delivery episiotomy was stitched in layers with chromic catgut number 1. Vaginal mucosa was stitched with continuous

sutures. After the delivery, in selective episiotomy group the perineum was examined to determine the presence of lateral, anterior, superficial or deep vaginal lacerations, and posterior lacerations classified as first-degree to fourth degree according to the currently accepted classification. On 3rd postnatal day, patient was discharged and was called for follow-up on 5th postnatal day and then after one month and three months for long-term post-partum complications. Details of each delivery were recorded in a proforma. After 24 hours of delivery, women were interviewed and perineal pain was evaluated using a visual pain scale and the need for analgesics was assessed. Visual analogue scale (VAS) for pain is a continuous scale comprised of a horizontal (HVAS) or vertical (VVAS) line, usually 10 centimeters (100 mm) in length anchored by “no pain” (score of 0) and “pain as bad as it could be” or “worst imaginable pain” (score of 10). Subject is asked: On a scale of 0 to 10, with 0 being no pain and 10 being the worst pain imaginable, what you rate your current pain?

For dyspareunia, women were asked if they had sexual intercourse during the last 4 weeks. Dyspareunia was considered as present when a woman gave an affirmative answer to the question ‘was sexual intercourse painful during the last couple of times?’ For ano-rectal incontinence participants were asked if there was any inability to control passage of faeces or flatus during the last 3 months of puerperium. For urinary incontinence participants were asked, ‘how often do you leak urine involuntarily?’ Incontinence was considered present whenever the participant gave the answer other than never.

Outcome measures

Our primary outcome measures were anterior vaginal trauma, 1st degree perineal tear, 2nd degree perineal tear, 3rd degree perineal tear, 4th degree perineal tear and Apgar score at 1 and 5 minutes. Secondary measures of outcome included consumption of analgesics, anal incontinence, urinary incontinence and dyspareunia.

Statistical analysis

Continuous variables with a normal distribution were summarized using the mean. The Student T test was used for comparing population characteristics for the normally distributed continuous variables. Categorical variables were expressed as percentages. The Chi square test was used for comparing categorical variables. P value of <0.05 was considered significant. Yate’s correction applied in those tests where any of the cell value was <5.

RESULTS

A total number of 463 women were assessed for eligibility, 286 women were eligible and 177 women were found not eligible. 286 women were enrolled for the study and were randomised. 86 women had to undergo

emergency caesarean delivery following randomisation and excluded from final analysis. 200 women, 100 in routine episiotomy group and 100 in selective episiotomy group were analysed (Figure 1). The two groups of women were similar with regard to control variables (Table 1) and there were no statistically significant differences between the groups.

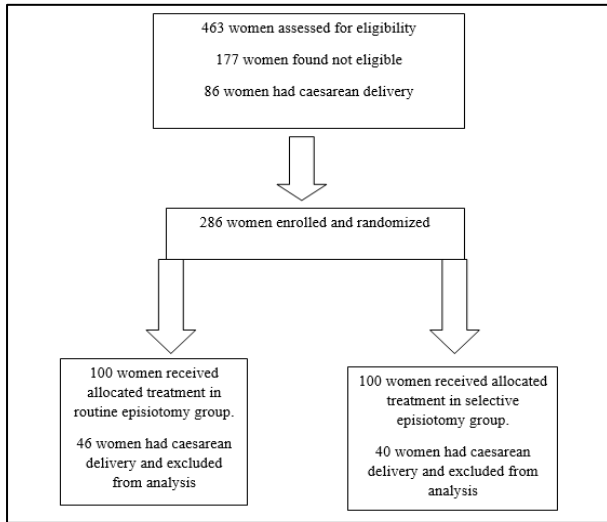


Figure 1: Trial profile.

Table 1: Showing baseline characteristics.

Variables	Routine episiotomy group (n=100)	Selective episiotomy group (n=100)	P value*
Age±SD** (years)	23.71±2.21	23.54±2.51	0.611
Religion			
Hindu	56	54	0.924
Muslim	42	46	0.749
Others	02	0	
Social status			
Low	66	70	0.797
Middle	44	30	0.130
Birth weight±SD (kg)	3.02±0.36	2.98±0.41	0.544

*P value χ^2 test and z test; SD** - Standard deviation

Primary outcome

Results for the primary outcome variable, are presented in (Table 2). As can be seen more women in selective episiotomy group had anterior vaginal tear and first-degree perineal tear and more women in routine episiotomy group had second degree perineal injury because of obvious reason. Only 3 women in routine episiotomy group delivered with intact perineum while 15 women in selective episiotomy group delivered with intact perineum. The difference between routine episiotomy group and selective episiotomy group was

statistically significant (p=0.006) There was no difference in occurrence of 3rd degree perineal tear and in Apgar score among the two groups. None of the women in either group had fourth degree perineal tear.

Table 2: Primary outcome measures.

Variables	Routine episiotomy group (n=100)	Selective episiotomy group (n=100)	P value*
Anterior vaginal wall tear	22	54	<0.0001
First degree perineal tear	05	16	0.021
Second degree perineal tear	90	64	<0.0001
Third degree perineal tear	02	05	0.442
Apgar score			
1 min. <7	09	13	0.498
5 min. <7	04	07	0.535

*P value – χ^2 test

Secondary outcome

Secondary outcome measures are shown in Table 3. As can be seen more women in routine episiotomy group used in analgesics on day 5 of delivery in comparison to selective episiotomy group. There was no difference in severity of perineal pain assessed by VAS, analgesic use on day 2 of delivery, anal incontinence, urinary incontinence, NICU admission of the neonate. 25 women (25%) from routine episiotomy group and 38 women (38%) from selective episiotomy group resumed coitus within 4 weeks. Out of 25 women in routine episiotomy group 21 (84%) women complained of dyspareunia while 26 (68.42%) women out of 38 women in selective episiotomy group complained of dyspareunia. The difference was not statistically significant (p=0.07).

Table 3: Secondary outcome measures.

Measures		Routine episiotomy group (n=100)	Selective episiotomy group (n=100)	P value*
Perineal pain				
VAS**	<6	39	53	0.065
score	>6	61	47	
Analgesic use on day 2		98	92	0.114
Analgesic use on day 5		65	48	0.022
Anal incontinence (flatus)		7	3	0.33
Urinary incontinence		15	20	0.456
NICU admission		6	9	0.591

*X² test ** Visual Analog Scale

DISCUSSION

100 women in routine episiotomy group and 100 women in selective episiotomy group received allocated treatment. The episiotomy rate was 90% in routine episiotomy group as 10 mothers delivered prior to episiotomy. In selective episiotomy group the episiotomy rate was 42%. An update of the Cochrane systemic review, which considers recent published and unpublished studies of good quality around the world, indicates the rate of the intervention, selective episiotomy, ranged from 8% to 59% whereas the rate of the comparator, routine episiotomy, ranged from 61% to 100%.³

In selective episiotomy group the episiotomy rate was 42% and additional 22% women suffered from 2nd degree perineal tear. Thus, occurrence of second-degree perineal injury was more common in routine episiotomy group (90% versus 64%; $p < 0.0001$). However, there was no difference in occurrence of 3rd degree perineal tear among the groups. On the other hand, more women in selective episiotomy group had intact perineum when compared with routine episiotomy group (3% versus 15%, $p = 0.006$). This finding is in agreement with the findings of recent Cochrane review that for women where an unassisted vaginal birth was anticipated, a policy of selective episiotomy may result in 30% fewer women experiencing severe perineal/vaginal trauma (RR 0.70, 95% CI 0.52 to 0.94; 5375 women; eight RCTs; low-certainty evidence).³ From neonatal point, there was no difference in Apgar score at 1 minute and at 5 minute of the babies born in two groups. Both selective and routine episiotomy have little or no effect on infants with Apgar score less than seven at five minutes (four trials, no events; 3908 women, moderate-certainty evidence.³

In our study more women in selective episiotomy group suffered from anterior vaginal wall tear (22% versus 54% $p < 0.0001$). This finding is consistent with the randomized control trial by Argentine Episiotomy Trial Collaborative Group in 1993 involving 2606 women.⁴

Our study shows there was no difference in occurrence of anal incontinence, dyspareunia, urinary incontinence among the groups. In 2005, Hartmann and colleagues analyzed 45 primary studies in their systematic review on outcomes of routine episiotomy analysis proved that there were no improvements in continence of urine or stools or in pelvic floor muscle function among women who had had episiotomy compared to those who had not.⁵

While the strength of our study was randomized design, the main limitation of our study was that patient allocation among the groups was not blinded. However,

different attending physicians with no connection to the research group were in charge of the clinical care of the patients and the group in which the patient was allocated was known only during the second stage of labor.

CONCLUSION

In conclusion, routine mediolateral episiotomy is associated with a higher incidence of perineal injuries without any added benefit for the mother and her baby and as perineal injuries known to have morbidities selective episiotomy use is therefore recommended.

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Ethical approval: The protocol for the research project had been approved by Ethics Committee of our institution (NRS Medical College) within which the work was undertaken

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